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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,818	12/21/2001	Mitsuhiro Nakamura	217323USOPCT	4756

22850 7590 12/24/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/926,818

Applicant(s)

NAKAMURA ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2, 4, 5, 7, 35 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 8-35, 41 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 4, 5, 7, 38-40 and 43 is/are allowed.
- 6) ☐ Claim(s) 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/03, 4/03 6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

Claims 2, 4, 5, 7-35, 38-45 are pending. Claims 2, 4, 5, 7, 38-40, 43-45 are considered on the merits. Claims 8-35, 41, 42 are withdrawn from consideration as being drawn to a non-elected invention.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 2/14/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 44, 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45, line 4, "said lipoproteins" does not have antecedent basis. It should be "said lipoprotein". Likewise in claims 4 and 5.

Claim 44, in the preamble the claim is said to be a method for quantitating free cholesterol and (an) esterified cholesterol. However, in the body of the claim, no assay which measures esterified cholesterol is seen. Thus, the claim is incomplete.

#### *Claim Rejections - 35 USC § 102*

Claim 45 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,479,249 [IDS].

Claim 45 is directed to a method for quantitating cholesterol in a specific lipoprotein in a sample comprising:  
causing cholesterol oxidase to convert only the free cholesterol, whereby the lipoproteins remain substantially unchanged, and measuring the cholesterol

which is present in the specific lipoprotein by using a substance which acts upon the specific lipoprotein only.

The reference is relied upon as explained below.

US 6,479,249 disclose a method where cholesterol oxidase is added to serum to convert free cholesterol, the specific lipoprotein (HDL) is substantially unchanged (col. 3, l. 15, l. 37). Then a surfactant is added which specifically acts on HDL (col. 4, l. 6), and the cholesterol in HDL is quantified.

Applicants request that that any rejection using a reference from the IDS file 4/14/03 be made non-final even if it is necessitated by amendment because the IDS submitted on 4/14/03 was not united with the application prior to the first office action,. A search of MPEP was made. No rule was found concerning making an office action non-final due to citation of a reference which has not been timely considered, if necessitated by claim amendment, was found. Claim 45 is a newly presented claim and is subject to a new rejection which may be made final.

#### ***Allowable Subject Matter***

Claims 2, 4, 5, 7, 38-40, 43, 44 are directed to allowable subject matter.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

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no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
December 18, 2003